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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,654	KUMAR ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *17-32,35-37,39-41 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 33-34, 38, 42, and 44-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/05;12/20/04;* 3/10/04; 6/25/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-59 are pending. The Applicant prior to Examination of the instant application withdrew claims 17-32, 35-37, 39-41, and 43 from consideration. **Claims 1-16, 33-34, 38, 42, and 44-59 are under consideration in the instant office action.**

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks TALWIN® (p 2, lines 23, 26, 27); REVIA® (p 3, line 6); POLYOX® (p 10, line 8; Tables 4, 6, and 11); EXPLOTAB® (p 15, line 28; p 18, line 8; Tables 8, 10-11, 14-16, and 23); CROSPOVIDONE® (p 15, line 30; Table 6, 9, 12-13, 17-19, 21, and 24); CAB-O-SIL® (p 16, line 9; Tables 4-6, and 8-26); LUBTRITAB® (p 16, line 32), and AVICEL® (Tables 4-6 and 8-24) have been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 10, 14, 33-34, 49, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite because it recites polyvinyl alcohol (PVA), hydroxypropyl methylcellulose (HPMC), and carbomer having specific viscosities. Viscosity is a property of a liquid or solution and PVA, HPMC, and carbomer are not liquids and are not identified as being in solution. Regarding solutions of polymers, a skilled artisan would require knowledge of a given polymer's molecular weight, the solvent in which said polymer is dissolved, and the concentration of said polymer to ascertain the solution viscosity. Therefore, the recitation of a specific range of viscosities for said polymers would be indefinite to a person of ordinary skill in the art at the time of the instant invention.

Claim 14 recites the limitation "the therapeutic composition of claim 1, wherein the nasal tissue irritating amount of surfactant" in line 2. There is insufficient antecedent basis for this limitation in the claim. Surfactant is not mentioned in claim 1.

Claim 33 is vague and indefinite because it recites "less than about 0.6 to 2.0 gm of zinc sulfate." The limitation of a value less than a recited range of values is inherently inconsistent, because the values greater than the lower limit would intrinsically violate the recited limitation. Therefore, a person of ordinary skill in the art would not be able to ascertain what amount of zinc sulfate Applicant intended.

Claims 49 and 59 are vague and indefinite because they utilize a Trademark to refer to a component of the recited composition, which is improper. Trademarks are associated with goods and services, which may change at any time based upon the manufacturers prerogative. Therefore, they are inherently indefinite, when used to refer to a composition of matter. See MPEP § 2173.05 (u).

Claim 34 is rejected, because it depends from rejected claim 33.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 8, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (US 2003/0125347).

Applicant claims a therapeutic pharmaceutical composition comprising (a) an analgesic (e.g. hydrocodone, antihistamines, and other opioids), (b) a gel-forming polymer (e.g. polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), or polyethylene oxide), (c) a nasal irritant, and (d) an emetic.

Anderson discloses a pharmaceutical composition and an oral dosage form comprising an **opiate and an irritant** as well as methods for treating pain and discouraging abuse of an opiate-containing composition by administration of a composition/oral dosage form comprising an opiate and an irritant (abstract). Opiate reads on opioid.

Anderson discloses that particularly preferred opiates include **hydrocodone, hydromorphone, and oxycodone**, and pharmaceutically acceptable salts thereof [0013].

Anderson discloses that suitable irritants include local and systemic irritants that are administered in powder form **by nasal or oral inhalation** or insufflation, and which may cause **swelling, redness, itching, burning, or stinging** in the **nasal** and/or buccal **tissues**. Preferred local irritants are capsaicinoids such as, for example, capsaicin. Suitable systemic irritants cause irritation by prompting discomfort in one or more physiological system without regard to the specific areas of the body, which contact the irritant. Substances that are systemic irritants to the gastrointestinal system may be selected to cause excessive or insufficient salivation, nausea, **emesis**, cramping, gas pain or discomfort, dyspepsia, heartburn, and/or diarrhea. Examples of such irritants include **emetics such as ipecac** [0024] through [0026].

Anderson discloses that the invented compositions may also include conventional excipients, including hydrophilic polymers, film-coating polymers, **disintegrants, and surfactants** [0033].

Anderson discloses that suitable hydrophilic polymers include, **HPMC and polyvinyl alcohols** (PVAs) [0035] and film-coating polymers, including **HPMC, POLYOX® polyethylene oxides**, sodium starch glycolate (EXPLOTAB®). HPMC, PVAs, and polyethylene

oxides are also inherently gel-forming polymers, as evidenced by Applicant's disclosure on page 9, lines 14-18 of the specification, wherein said polymers are identified as gel-forming polymers.

Anderson discloses that suitable **disintegrants** include **CROSPOVIDONE®**, PVA, sodium starch glycolate (e.g. EXPLOTAB®), etc. [0039]. Suitable **surfactants** include ionic surfactants, such as **sodium dodecyl sulfate** [0040]. Sodium dodecyl sulfate is another name for sodium lauryl sulfate, and in addition to being a surfactant is inherently a nasal irritant.

Anderson discloses that the invented compositions may be in one of the following dosage forms suitable for the oral administration of an opiate composition: **tablet, capsule**, **sprinkle or multiparticulate formulation (e.g. granules, spheroids, beads, pellets or the like), or gelatin capsules** [0042]. Tablets and capsules are unit dose dosage forms.

Claims 1-8, 12, 38, 44-47, 50-53, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Bartholomäus et al. (WO 04/037259). The English translation of WO 04/037259 was provided by the Applicant in the IDS submitted on December 20, 2004.

Applicant claims a therapeutic pharmaceutical composition comprising (a) an analgesic (e.g. hydrocodone, antihistamines, and other opioids), (b) a gel-forming polymer (e.g. polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), or polyethylene oxide), (c) a nasal irritant, and (d) an emetic.

Bartholomäus discloses a dosage form, which in addition to the **active agent**, comprise (a) at least **one substance that irritates the nasal and/or pharyngeal region** (i.e. nasal irritant); (b) at least one agent that increase viscosity, which **forms a gel in an extract obtained from a**

minimal quantity of aqueous liquid; (c) at least one antagonist for the active agent; and (d) **at least one emetic** (abstract; pg. 2 of translation).

Bartholomäus discloses that components (a) and (b) of the dosage form may be contained within subunit (A) and that components (c) and (d) may be contained within subunit (B) (pg. 12-13, paragraph beginning at the bottom of page 12 and ending at the top of page 13 of the translation). Bartholomäus discloses that if a barrier layer (D) is not present for use in controlling the release of the emetic and/or the drug antagonist, components (d) and (c), respectively, then the materials of subunit B are selected so that the release of (c) and/or (d) is ruled out (pg. 15, last two paragraphs). Examples of especially suitable such materials include **HPMC, polyethylene oxide, and polyvinyl alcohol** (2nd paragraph beginning on page 16 of the translation).

Bartholomäus discloses in Examples 19 and 20 exemplify dry coated tablets comprising (a) a core comprising emetine (an emetic) and hydrogenated castor oil and (b) a dry coating comprising 60 mg of **morphine sulfate pentahydrate** (example 19) or 30 mg of **oxycodone hydrochloride** (claim 20) (both are analgesic opioids), **methyl hydroxypropyl cellulose** (i.e. HPMC, a gel-forming polymer), **cayenne pepper** (a nasal irritant), at least one **surfactant** (magnesium stearate in Examples 19-20 and stearyl alcohol in Example 20), and other ingredients (pgs. 24-25 of translation). Bartholomäus discloses other exemplary dosage forms including capsules, micropellets, microcapsules, etc (see claim 20 on page 41 of the translation). Tablets, capsules, etc. are examples of unit dose forms.

It is noted that claim 5 of WO 04/037259 recites several analgesics including, **alfentanil, buprenorphine, butorphanol, codeine, dihydrocodeine, dihydromorphine, fentanyl,**

hydrocodone, hydromorphone, levacetylmethadol, levomethadone, lofentanil, levorphanol, methadone, morphine, nalbuphen, oxymorphone, pentazocine, pethidine, propoxyphene, remifantanil, sufentanil, tilidine, tramadol, and esters, ethers, salts, and solvates thereof.

Regarding the properties recited in part (c) of claims 44 and 50 and in dependent claims thereof, these properties are inherent to the recited composition. The prior art discloses this composition and therefore the prior art composition inherently has the property of preventing less than 30% or 45% of the opioid from being recovered upon contact with 15 ml of water.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 6-7, 9-15, 38, and 44-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0125347).

Applicant Claims

Applicant claims a therapeutic pharmaceutical composition comprising (a) an analgesic (e.g. hydrocodone, antihistamines, and other opioids), (b) a gel-forming polymer (e.g. polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), or polyethylene oxide), (c) a nasal irritant, and (d) an emetic.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Many of Anderson's relevant teachings/disclosures have been set forth above in the previous rejection under 35 U.S.C. § 102(e). Additional teachings are presented herein. Anderson discloses suitable opiates for use in his invention, including: **alfentanil**, **buprenorphine**, **butorphanol**, **codeine**, **dezocine**, **dihydrocodeine**, **dihydromorphine**, **hydrocodone**, **hydromorphone**, **levorphanol**, **lofentanil**, **meperidine**, **methadone**, **morphine**, **oxycodone**, **pentazocine**, **pro-poxyphene**, **sufentanil**, **tilidine**, and **tramadol** [0012]. Anderson also teaches that the composition preferably comprises as the analgesic only one or more opiates

[0015]. The amount of opiate in Anderson's compositions will be an amount ranging from about 0.1 to about 20 wt. %, even when combined with other therapeutically active ingredients [0017].

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Anderson does not anticipate the cited claims in the instant rejection, because the analgesics of claims 7-8 are present in a long list; the amount of analgesic that is disclosed by Anderson is disclosed as a wt% of the total composition, instead of an absolute mass; and Anderson does not disclose specific amounts of surfactant or specific polymer molecular weights.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to select morphine or another known opiate analgesic from the list taught by Anderson, because these compounds belong to the same class of pharmaceuticals (i.e. opioid analgesic) and therefore would be expected to exhibit the same or similar therapeutic properties upon substitution for one of the three particularly preferred opiates disclosed by Anderson (i.e. oxycodone, hydrocodone, and hydromorphone). Furthermore, because these other opiates, taught by Anderson in paragraph [0012] are known analgesics, a person of ordinary skill in the art would have had a reasonable expectation of success upon substitution of these for any of the three particularly preferred opiates disclosed by Anderson.

Anderson teaches compositions comprising one or more polymers, including HPMC, PVA, and polyethylene oxide, which are gel-forming polymers. Anderson is silent with regards to the teaching of the molecular weight of these polymers. However, it would have been obvious to a skilled artisan to optimize polymer molecular weight to obtain compositions having the desired property (e.g. viscosity). Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal polymer molecular weight needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of polymer molecular weight would have been obvious at the time of applicant's invention.

It would have been apparent to a person of ordinary skill in the art at the time of the instant invention that the wt. % range taught by Anderson would encompass or make obvious the mass amounts of opioid recited in claim 4 of the instant application, because it is typical that pharmaceutical compositions for oral administration have total masses of amounts of a gram of less (see Example 1 in US 2005/0063909; Wright IV et al). It is also noted that Anderson is silent as to the amount of surfactant used in his compositions. However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed

parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Finally, in claims 44, 50, and dependent claims thereof, the Applicant recites that the claimed compositions exhibit a property of preventing the recovery of a specified percentage of the total amount of opiate contained within said composition upon contact with 15 ml of water. It would have been apparent to a skilled artisan that the compositions disclosed by the prior comprising an opioid analgesic, a gel-forming polymer, and a nasal irritant would also have this property, because the properties of a composition cannot be separated from the composition. Therefore the Examiner concludes that claims 4, 6-15, 38, and 44-59 are *prima facie* obvious over the teachings of Anderson et al. (US 2003/0125347).

Claims 9-11, 13, 54, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomäus et al. (WO 04/037259).

Applicant Claims

Applicant claims a therapeutic pharmaceutical composition comprising (a) an analgesic (e.g. hydrocodone, antihistamines, and other opioids), (b) a gel-forming polymer (e.g. polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), or polyethylene oxide), (c) a nasal irritant, and (d) an emetic.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings/disclosures of Bartholomäus have been set forth above in the rejection of claims 1-8, 12, 38, 44-47, 50-53, and 55 are rejected under 35 U.S.C. 102(e).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Bartholomäus does not exemplify compositions comprising polyvinyl alcohol or polyethylene oxide. Bartholomäus does not disclose the molecular weights of polyvinyl alcohol, polyethylene oxide, of HPMC polymers used in his compositions. Bartholomäus also does not disclose amounts of surfactant ranging from 1-5 % by weight.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Bartholomäus teaches compositions comprising polymers, including HPMC, PVA, and polyethylene oxide, which are gel-forming polymers. Compositions comprising HPMC are exemplified in Bartholomäus' specification. Regarding, PVA and polyethylene oxide, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to use these polymers, because they are taught as being especially suitable materials for subunit B, when a barrier layer (D) is not present. Bartholomäus is silent with regards to the teaching of the molecular weight of these polymers. However, it would have been obvious to a skilled artisan to optimize polymer molecular weight to obtain compositions having the desired property (e.g. viscosity). Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal polymer molecular weight needed to achieve the desired results. Thus,

absent some demonstration of unexpected results from the claimed parameters, the optimization of polymer molecular weight would have been obvious at the time of applicant's invention.

It is noted that many of the compositions disclosed by Bartholomäus comprise surfactants. For example, Example 19 comprises magnesium stearate present in an amount of approximately 0.01% by weight (magnesium stearate) and the composition of Example 20 has ~0.01 wt. % magnesium stearate surfactant and approximately 18% by weight of stearyl alcohol surfactant. However, similarly to the arguments presented above for polymer molecular weight, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to optimize the amount of surfactant contained within a given composition, because the optimization of the amount of an ingredient in a composition is a routine practice in the art.

Claims 16 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0125347) as applied to claims 4, 6-15, 38, and 44-59 above, and further in view of Porter (U.S. Patent No. 4,175,119).

Applicant Claims

Applicant claims a therapeutic pharmaceutical composition comprising (a) an analgesic (e.g. hydrocodone, antihistamines, and other opioids), (b) a gel-forming polymer (e.g. polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), or polyethylene oxide), (c) a nasal irritant, and (d) zinc sulfate as an emetic.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings/disclosures of Anderson have been set forth above in the previous two rejections under 35 U.S.C. § 102(e) and/or §103(a). Porter teaches pharmaceutical compositions and methods employing said compositions to prevent accidental and intentional overdosage with psychoactive drugs, wherein the composition is coated with a sufficient amount of an **emetic chemical** to cause emesis upon consumption of an overdosage of said composition (title and abstract). Porter teaches that the emetic is preferably comprised of a major portion of methyl cephaeline and cephaeline, and a minor portion of psychotrine (col. 2, lines 21-23), and that these are more effective than other **known emetics, including zinc sulfate** (col. 3, lines 9-12). Porter teaches that narcotics (e.g. oxycodone, hydromorphone, codeine (codine), etc.) are examples of psychoactive therapeutic drugs, which may be included in his invented compositions. Porter claims compositions wherein the therapeutic agent is an analgesic narcotic, including oxycodone, hydromorphine, codeine, and mixtures thereof (see Porter's claims 21 and 24-25).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Anderson is lacking in the teaching of zinc sulfate. This deficiency is cured by the teaching of Porter that zinc sulfate is an emetic.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Anderson and Porter, because both inventors teach

pharmaceutical compositions comprising an opioid analgesic (e.g. oxycodone) and an emetic. Although Porter teaches that zinc sulfate is not the preferred emetic, this is not considered to teach away from the use of zinc sulfate as an emetic, but rather Porter's preference to use a different emetic. It would have been obvious to a skilled artisan to use zinc sulfate in lieu of another emetic, because it would be expected to induce emesis upon ingestion. Regarding the amount of zinc sulfate within a given composition, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results (e.g. emesis upon ingestion of an overdosage of a given composition). Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 16 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomäus et al. (WO 04/037259) as applied to claims 9-11, 13, 54, and 57 above, and further in view of Porter (U.S. Patent No. 4,175,119).

Applicant Claims

Applicant claims a therapeutic pharmaceutical composition comprising (a) an analgesic (e.g. hydrocodone, antihistamines, and other opioids), (b) a gel-forming polymer (e.g. polyvinyl alcohol, hydroxypropyl methylcellulose (HPMC), or polyethylene oxide), (c) a nasal irritant, and (d) zinc sulfate as an emetic.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings/disclosures of Bartholomäus have been set forth above in the previous rejections under 35 U.S.C. § 102(e) and/or §103(a) and the teachings of Porter were set forth above in the preceding rejection under 35 U.S.C. 103(a).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Bartholomäus is lacking in the teaching of zinc sulfate. This deficiency is cured by the teaching of Porter that zinc sulfate is an emetic.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Bartholomäus and Porter, because both inventors teach pharmaceutical compositions comprising an opioid analgesic (e.g. oxycodone) and an emetic. Although Porter teaches that zinc sulfate is not the preferred emetic, this is not considered to teach away from the use of zinc sulfate as an emetic, but rather Porter's preference to use a different emetic. It would have been obvious to a skilled artisan to use zinc sulfate in lieu of another emetic, because it would be expected to induce emesis upon ingestion. A skilled artisan would have had a reasonable expectation of success upon combination of the teachings of Bartholomäus and Porter and the use of zinc sulfate, because of the similarities described above between the prior art references and the knowledge that zinc sulfate is an emetic. Regarding the

amount of zinc sulfate within a given composition, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results (e.g. emesis upon ingestion of an overdosage of a given composition). Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Conclusion

Claims 1-16, 33-34, 38, 42, and 44-59 are rejected. No claims under consideration in the instant office action are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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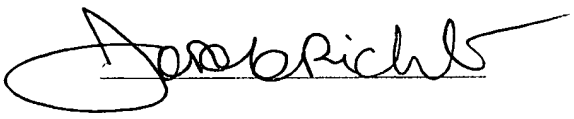

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